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Dated 7 July 2004

Patents Form 1/77

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1/77

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet, from the Patent Office to help you fill in this form)

The Patent Office
Cardiff Road
Newport
South Wales NP10 8QQ

1. Your reference — LB1863

2. Patent application number *(The Patent Office will fill in this part)* — 0321911.0

195EP03 E838423-1 002806
P01/7700 0.00-0321911.0

19 SEP 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Anthony Arthur WILLS
10 Greenham Road
London
N10 1LP
United Kingdom (GB)

Patents ADP number *(if you know it)* 6399968001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — Improvements in or relating to medical devices

5. Name of your agent *(if you have one)*

~~Barker Brettell~~
KILBURN & STRODE

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

~~10-12 Priests Bridge~~
~~London~~
~~SW15 5JE~~
20 RED LION STREET
LONDON
WC1R 4PJ

Patents ADP number *(if you know it)* ~~7442494003~~ ✓ 125001

6. Priority: Complete this section if you are declaring priority from one or more earlier patent applications, filed in the last 12 months.

Country	Priority application number *(if you know it)*	Date of Filing *(day/month/year)*
United Kingdom	0314247.8	19th June 2003
United Kingdom	0314920.0	26th June 2003

7. Divisionals, etc: Complete this section only if this application is a divisional application or resulted from an entitlement dispute (see note f)

Number of earlier application	Date of filing *(day/month/year)*

8. Is a Patents Form 7/77 (Statement of inventorship and of right to grant of a patent) required in support of this request? *Answer 'Yes' if:*
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
Otherwise answer NO (See note(d)

No

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	7 ✓
Claim(s)	2 ✓
Abstract	1 ✓
Drawing(s)	1 + 1 ✓

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination *(Patents Form 9/77)*	1 ✓
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature: Barker Brettell — Date: 18 September 2003

12. Name and daytime telephone number of person to contact in the United Kingdom: Lance Butler — Tel: 0121 456 1364

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Notes

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IMPROVEMENTS IN OR RELATING TO MEDICAL DEVICES

[0001] This invention concerns improvements in or relating to medical devices and in particular, but not exclusively to medical devices intended for single usage only.

[0002] Any medical establishment, for example a hospital, should be the focus for scrupulous hygiene with a view to minimising the risk of infection especially in patients following surgery when they are most vulnerable. The relatively and worryingly high incidence of for example *MRSA* in hospitals is of great concern since treatment is exceedingly difficult and in some instances the infection results in fatality.

[0003] In the practice of modern medicine, many devices that are widely available are of the single use category, namely that once used they should be discarded to ensure destruction before nominally forbidden further usage.

[0004] Devices such for example as cannulas, catheters and other relatively minor medical appliances are usually supplied in a sterilised packaging and when extracted they become subject to the rigours of the ambient atmosphere and more importantly to the specific medical procedures for which they are designed. The spread of infection can occur when devices of this kind are used more than the prescribed single occasion. This abuse of single use devices is to be deprecated, but some measures have been applied with a view to preventing multiple use. For example, in the case of hypodermic needles frangible parts are employed to the extent that any attempted further use effects breakage rendering the needle incapable of deployment.

Equally in spare parts surgery, for example hip prostheses, some manufacturers produce the relevant part in a material which is not susceptible of sterilisation, and any attempt to autoclave the part results in its disintegration. Clearly an approach of that kind is acceptable for spare parts, but for conventional medical devices of relatively minor value it would be unnecessarily burdensome to produce them from sophisticated materials.

[0005] There are considerable financial pressures placed upon medical personnel to re-use single-use medical devices as the savings in expenditure can be significant, but the consequences of inadequate sterilisation can be catastrophic.

[0006] An object of the present invention is to provide a medical device having means for informing the user of the status of the device in terms of further usage.

[0007] According to the invention there is provided a medical device including a latent marking which becomes visible during or following first usage of the device.

[0008] The medical device may of any description for use in any medical procedures requiring contact with a patient, for example a cannula, a catheter, a speculum, a spatula, even face masks and protective gloves etc. most of which are initially encased within and supplied in sterile packaging.

[0009] The latent marking may be in the form of an etching on the device *per se* or in the alternative may be in the form of a label irremovably attached to a part of the medical device.

The latent marking may be provided with a sealing strip or film to protect it and prevent or assist in preventing premature damage that would otherwise cause degradation by wear. The latent marking is designed to withstand any attempt to recycle the medical device, namely the latent marking will survive throughout the period of use of the device and thereafter.

[0010] The label is conveniently provided with an adhesive of a strength sufficient to withstand handling and exposure to any physical abuse which may be designed to remove the latent marking.

[0011] In the event that labelling is employed and additional or secondary irremovable latent marking may be provided beneath the label such that if the label is removed a final warning is displayed to the user that the relevant device has been used and should be discarded.

[0012] The latent marking is designed to be gas, light or temperature sensitive in terms of the marking becoming visible within a predetermined time frame following exposure, for example to the atmosphere, once it has been removed from its packaging. The packaging protects the latent marking from inadvertent exposure to the atmospheric conditions that activate the sensitivity of the latent marking. The marking may be so arranged as to become visible upon being irreversibly triggered by exposure to for example light or the ambient atmosphere, whether or not that exposure prevails. In the alternative, the marking may become visible over a period of time following and during exposure to for example light or the ambient atmosphere.

[0013] The marking may be symbolic and/or may be in the form of wording that provides a suitable warning against further usage. The symbol used for warning the user of the spent status of the medical device may be conventional, *e.g.* a skull and cross bones or a biohazard logo, and the wording may be by way of information that the current period of use should be final. In the alternative the latent marking may be a dye or light-sensitive chemical that changes colour upon or during exposure to gas, light or temperature.

[0014] The marking may conveniently be made with dyes or suitable chemicals having the requisite sensitivity as indicated *supra*. For example chemicals used in the photographic industry may be suitable for this purpose but are required to be non-toxic in the light of their intended usage or be appropriately sealed from bodily fluids. Generally the latent marking as with the medical device to which it is applied must not compromise the clinical condition or the safety of patients or of other persons during the lifetime of the device in question. Further the latent marking must be compatible with biological tissues, cells and body fluids, taking account of the intended purpose of the device in question.

[0015] It is of course well known to employ chemicals in or on strip material, for example film, for reaction to light or exposure to the ambient atmosphere as is known from photographic technology. It is also known to provide personal admission or attendance badges that upon expiry of the valid time period reveal readable information concerning the time-out or void status of the badge.

[0016] Also available are temperature sensitive labels that provide a visual indication as to the temperature level of the items to which they have been applied. For example in washing crockery or other items a label attached to a plate will change colour if the required temperature for sterilisation has been attained. This procedure is of value in hospital catering functions with a view to ensuring a predetermined level of cleanliness and hygiene. In engineering applications labels may be attached to for example casings and if the acceptable temperature level is exceeded the colour of the label changes revealing also the temperature attained.

[0017] The present invention, however, is directed to a particular and novel and inventive application of safety marking for single use medical devices.

[0018] The present invention embraces any medical device provided with a latent marking howsoever produced of the kind which becomes visible as hereinbefore defined during or following use.

[0019] By way of example one medical device according to the invention is described below with reference to the accompanying drawings in which:

[0020] Figure 1 is an isometric view of the medical device immediately following extraction from its packaging; and

[0021] Figure 2 is an isometric view of the medical device after a predetermined period of usage.

[0022] Referring to Figure 1 there is depicted a medical device 1 which in this example is a guide for example for a hypodermic needle (not shown) that provides for an accurate focus and steadiness to reduce patient stress. The device 1 is shown as having been removed from its gas tight packaging ready for use and it will be seen that the surface of the device is clear of any marking.

[0023] However the device 1 is provided with a latent marking which remains invisible when the device is packaged and immediately following unwrapping. However, once the device 1 is exposed to the ambient conditions, either light or gas, *e.g.* air, the latent marking 2 begins to appear and after a set period of time becomes completely visible to reveal a warning as illustrated by way of example only in Figure 2.

[0024] As will be seen, the marking 2 conveys the message that the device has been used and should be disposed of safely and draws attention to itself by being flanked by the skull and crossbones symbols warning of danger. It is of course to be understood that the message may be couched in different words, but it should convey the same intent, namely to warn that the device should be destroyed having already been used. It also serves as a reminder to the actual user that it should be discarded following completion of the relevant procedure.

[0025] The latent marking 2 may be gas, light or heat sensitive. Conveniently the disclosure of the latent marking by such exposure may be irreversibly triggered thereby in order to

prevent any steps subsequently being taken to negate or arrest the process.

[0026] The latent marking 2 may either be etched into the surface of the device or be in the form of a label irremovably adhered to that surface. In either or both cases a protective seal may be provided over the marking to prevent tampering and protect against inadvertent damage or premature activation. The seal may be a film. In any case the seal is of such material as to be light or gas permeable to enable the latent marking to function as indicated above.

[0027] The latent marking 2 may be applied in the form of selected dyes chosen for the characteristic of being invisible in one medium and visible upon exposure to gas, light or heat in another medium. In the alternative, the latent marking may include chemicals which upon exposure become visible as indicated above.

[0028] The present invention thus provides for the security of medical devices by giving both a visual indication as to their usage and a warning that they should be discarded in the interests of patient safety. Further the invention represents a relatively simple and yet effective manner of indicating that the use of the device is no longer valid and would compromise the clinical condition or the safety of the patient.

CLAIMS

1. A medical device including a latent marking which becomes visible during or following first usage of the device.

2. A medical device according to Claim 1 in which the marking is adapted to become visible upon exposure to ambient conditions.

3. A medical device according to Claim 2 in which the ambient conditions include light, the atmosphere and/or temperature.

4. A medical device according to Claim 2 or 3 in which the latent marking is adapted to become visible upon exposure to air.

5. A medical device according to Claim 2 or 3 in which the latent marking is adapted to become visible upon exposure to light.

6. A medical device according to Claim 5 in which the exposure to light is adapted to trigger the irreversible appearance of the latent marking.

7. A medical device according to any one of the preceding claims in which the device is packaged prior to use.

8. A medical device according to Claim 7 in which the removal from the packaging occasions exposure to ambient conditions.

9. A medical device according to any one of the preceding claims in which the latent marking is etched into the surface of the device.

10. A medical device according to any one of the preceding Claims 1 to 8 in which the latent marking is carried on a label irremovably adhered to the surface of the device.

11. A medical device according to Claims 9 or 10 in which the latent marking comprises dyes applied in such manner to yield in the visible spectrum following exposure a warning message.

12. A medical device according to Claims 9 or 10 in which the latent marking comprises chemicals applied in such manner to yield in the visible spectrum following exposure a warning message.

13. A medical device substantially as hereinbefore described with reference to the accompanying drawings.

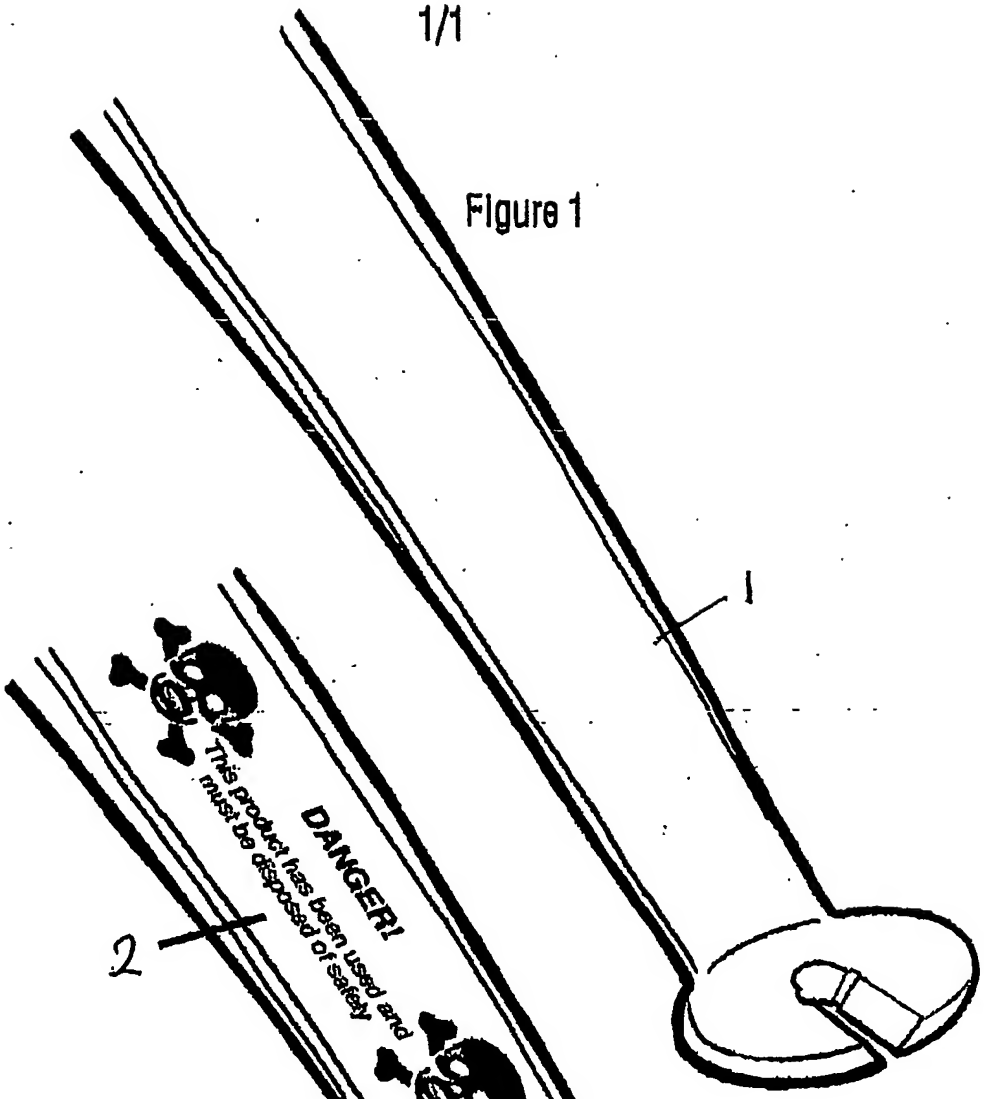
ABSTRACT OF THE INVENTION

IMPROVEMENTS IN OR RELATING TO MEDICAL DEVICES

A medical device 1 when packaged carries an invisible latent marking 2, which becomes visible upon exposure to ambient conditions of usage.

(Figure 2 to be used)

Figure 1



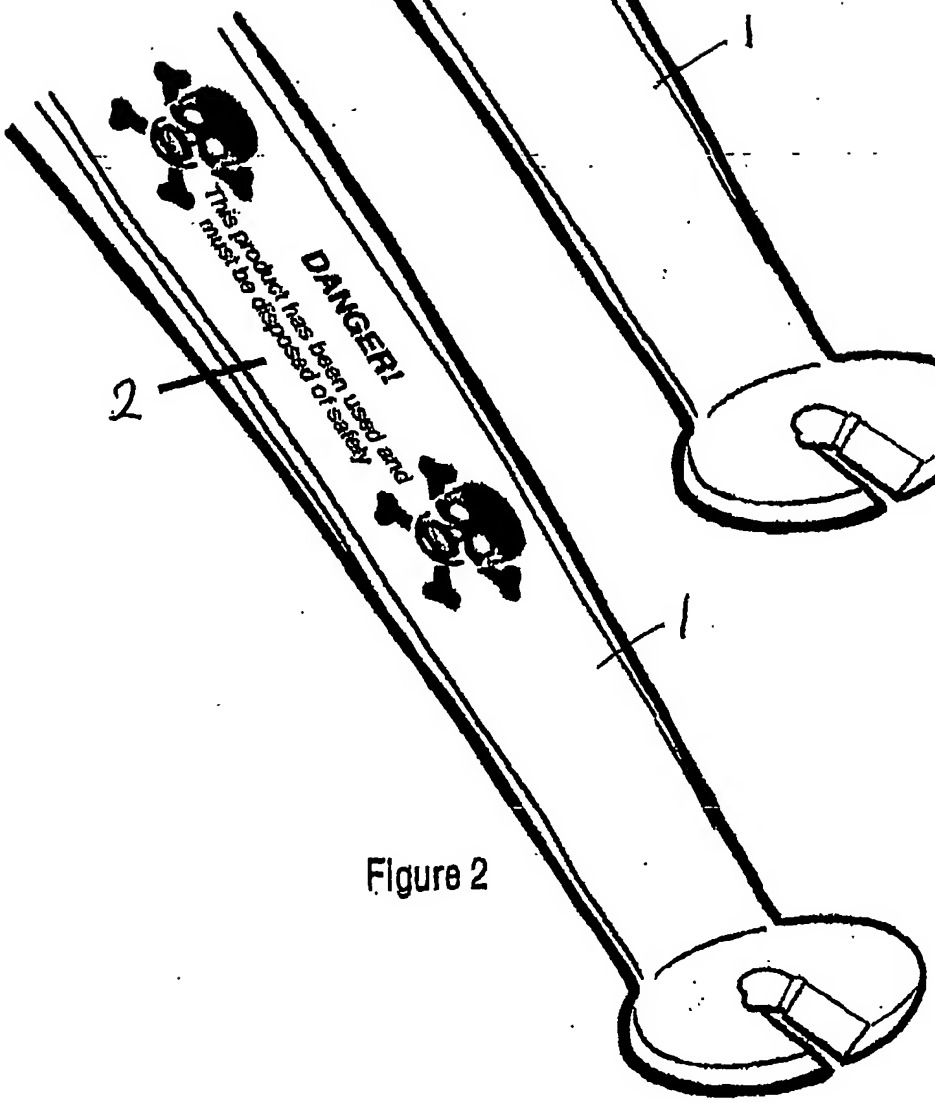


Figure 2